

The opinion in support of the decision being entered today was not written for publication in a law journal and is not binding precedent of the Board.

Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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MAILED

JAN 31 2002

Ex parte THOMAS C. ARTER, JOHN C. MAUCK,  
JAMES R. SCHAEFFER and ROBERT F. WINTERKORN

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Appeal No. 2001-2337  
Application No. 08/493,442

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

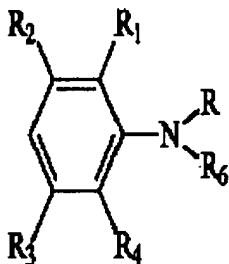
DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from an examiner's final rejection of claims 9 through 11 and 13 through 17.

Claim 9 is representative of the subject matter on appeal:

9. A dry multilayer analytical element for the determination of acetaminophen in an aqueous fluid, comprising a support having thereon, in order from said support and in fluid contact:

(a) a layer having therein (i) an arylacylamidase enzyme; (ii) a ferricyanide capable of oxidatively coupling paraaminophenol to a color-forming coupling agent to form a color compound; and (iii) a water-soluble, color-forming coupling agent, at least one layer comprising gelatin and said water-soluble, color-forming coupling agent having the general formula:



wherein R is a water-solubilizing group selected from (1) – (CH<sub>2</sub>)<sub>n</sub>X, where n is 1 to 5, X is either (I) –SO<sub>3</sub>M where M is hydrogen, an alkali metal, an alkaline earth metal or an ammonium (NH<sub>4</sub><sup>+</sup>) cation, or (II) (–OCH<sub>2</sub>CH<sub>2</sub>)<sub>y</sub>OH where y is 2 to 5; and (2) – N(R<sub>7</sub>)<sub>3</sub>+Z<sup>–</sup> where each R<sub>7</sub> is independently selected from alkyl of 1 to 4 carbon atoms, and Z is an acid anion;

R<sub>1</sub> and R<sub>6</sub> are taken together to represent an ethylene, trimethylene, or tetramethylene group which forms a partially saturated ring; and

R<sub>2</sub>, R<sub>3</sub>, and R<sub>4</sub> are independently selected from hydrogen, alkyl of 1 to 4 carbon atoms, and alkoxy of 1 to 4 carbon atoms;

(b) a porous spreading layer; and

(c) a buffer which maintains the pH of the element in a range of between about 6.5 to 8.5.

The references relied on by the examiner are:

Matsumoto et al. (Matsumoto)	4,675,290	Jun. 23, 1987
Kawaguchi et al. (Kawaguchi)	4,820,649	Apr. 11, 1989
Batz et al. (Batz)	4,845,030	Jul. 04, 1989
deCastro et al. (deCastro)	4,999,288	Mar. 12, 1991

Hammond et al. (Hammond), "Development of an Enzyme-Based Assay for Acetaminophen," Analytical Biochemistry, Vol. 143 pp. 152-157 (1984)

Arter et al. (Arter), "Development of a Multilayered Colorimetric Assay for Serum Acetaminophen," Clinical Chemistry, Vol. 39, No. 6, p. 1230 (1993)

#### GROUND OF REJECTION

Claims 9 through 11, 14 and 17 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies on Arter, Hammond, Matsumoto, deCastro and Batz.

Claims 13, 15 and 16 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies on Arter, Hammond, Matsumoto, deCastro, Batz and Kawaguchi.

On consideration of the record, we reverse.

#### BACKGROUND

The present invention "relates to a spectrophotometric assay for the detection of acetaminophen in aqueous fluids which is carried out with a dry analytical element" (specification, page 1). "An advantage of the invention is that the water-soluble coupling agent and either the enzyme catalyzed oxidative coupling or the ferricyanide coupling allow for a rapid reaction" (specification, page 4).

REJECTION OF CLAIMS 9 THROUGH 11, 14 AND 17 UNDER 35 U.S.C. § 103

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). Patentability of a claim under 35 U.S.C. § 103 must be premised upon considering the subject matter of a claim "as a whole." Furthermore, as stated in Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996) (citation omitted): "It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references." With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

Claim 9 requires the use of ferricyanide. The examiner relies on the use of cyanoferrate compounds in Hammond and Matsumoto to meet this limitation. Hammond teaches the use of hexacyanoferrate complexes in acetaminophen assays (Hammond, page 153, col. 2; appeal brief, page 5). Matsumoto also teaches the use of cyanoferrate complexes, such as pentacyanoferric complex, in acetaminophen assays (Matsumoto, col. 9, line 57 and col. 10, lines 3-5; appeal brief, page 6). However, the examiner has not provided a fact-based explanation establishing that these compounds

are or include ferricyanide as required by claim 9.

In addition, claim 9 also requires "at least one layer comprising gelatin." The examiner does not point to any disclosure in any of the relied upon references that would have taught or suggested this limitation.

In reviewing the examiner's answer, we find that the examiner's analysis does not consider the subject matter of a claim "as a whole" as required by the statute. Accordingly, we reverse.

#### REJECTION OF CLAIMS 13, 15 AND 16 UNDER 35 U.S.C. § 103

We also reverse this rejection since it is predicated on the references applied to independent claim 9. The examiner's reliance on the reference to Kawaguchi does not overcome the deficiencies noted above.

#### OTHER ISSUES

Since the examiner did not meet the initial burden of presenting a prima facie case of obviousness, we find no need to consider appellants' argument or evidence of unexpected results. However, we are compelled to note that the examiner did not adequately consider the appellants' argument or evidence of non-obviousness (appeal brief, pages 9 through 11). According to the examiner, "in order for evidence of unexpected results to be sufficient to rebut a prima facie case of obviousness, the evidence must be commensurate in scope with the claims" (examiner's answer, paragraph bridging pages 10 and 11). While the examiner's statement is correct, it appears that the examiner has misapprehended and as a consequence misapplied this

legal standard.

First, a conclusion of prima facie obviousness does not end a patentability determination under 35 U.S.C. § 103. As stated in In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986):

If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed. In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

Here, appellants have presented comparative examples in an attempt to establish unexpected results for the claimed invention. Specifically, appellants have provided evidence and argument that “the ferricyanide oxidizing agent, as used in this invention, would have been expected to fail as a suitably rapid oxidizing agent within the neutral pH used here” and that, instead, “ the ferricyanide used in this element permits the very rapid generation of a detectable colored signal – in only 57 seconds” (appeal brief, page 10; specification, page 4, line 29).

It is true that objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support. In re Clemens, 622 F.2d 1029, 1035, 206 USPQ 289, 296 (CCPA 1980); In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978); In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); In re Tiffin, 448 F.2d 791, 792, 171 USPQ 294, 294 (CCPA 1971). In applying this legal principle to the facts at hand it is apparent that merely stating that the evidence is not commensurate in scope with the claims without

providing an analysis of the scope of the evidence and the scope of the claims under review does not allow for a reasoned review of the examiner's position. To the extent the examiner's dismissal of the evidence is on the basis that the claims on appeal do not state that the gelatin of the element is not hardened or do not recite a determination time, he has not explained why the claims need to be so limited. If the examiner is of the opinion that the claims need to recite the underlying basis or mechanism or specific result demonstrated in order for the evidence to be given weight and effect, he has not relied upon judicial precedent or any other authority in support of that opinion. In most cases, issues of whether evidence of unexpected results is commensurate in scope with the claims arises in the context of the scope of the experimental work performed which demonstrates the purported unexpected result in relation to the scope of the pending claims, not whether the claims are limited to recite the purported unexpected result. In other words, when a claim is commensurate in scope with the proffered evidence of non-obviousness, the claim will necessarily produce or possess the result urged to be unexpected.

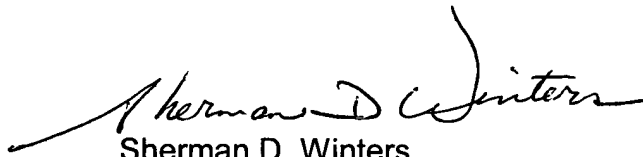
A second point needs to be considered by the examiner and appellants when the case is returned to the examiner. As indicated above, the examiner did not properly account for the claim requirement that the element contain gelatin. In reversing the rejection we do not mean that the references do not describe a test element containing gelatin, only that the examiner has failed to explain where the applied prior art teaches or suggests this requirement. We note that Arter used a Kodak Ektachem Clinical

Appeal No. 2001-2337  
Application No. 07/493,442

Chemistry Slide. Neither the examiner nor appellants favored the record with an explanation of the various constituents of that commercial product. It may be that the slide contains a gelatin layer. Appellants and the examiner should work together to ensure that the record accurately reflects the full disclosure of the applied references.

The decision of the examiner is reversed.

REVERSED



Sherman D. Winters  
Administrative Patent Judge



William F. Smith  
Administrative Patent Judge



Donald E. Adams  
Administrative Patent Judge

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Appeal No. 2001-2337  
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